ANNALS OF SURGERY
Vol. 233, No. 1, 45–50

Bile Leakage After Hepatic Resection

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Objective
To identify the perioperative risk factors for postoperative bile leakage after hepatic resection, to evaluate the intraoperative bile leakage test as a preventive measure, and to propose a treatment strategy for postoperative bile leakage according to the outcome of these patients.

Summary Background Data
Bile leakage remains a common cause of major complications after hepatic resection.

Methods
Between January 1985 and June 1999, 781 hepatic resections without bilioenteric anastomosis were performed at the authors' institution. Perioperative risk factors related to postoperative bile leakage were identified using univariate and multivariate analysis. The characteristics of patients with intractable bile leakage and the effect of intraoperative bile leakage test were also examined. Management was evaluated in relation to the outcomes and the clinical characteristics of the patients with bile leakage.

Results
Bile leakage developed in 31 (4.0%) of 781 hepatic resections. This complication carried high risks for surgical death (two patients [6.5%] died). The stepwise logistic regression analysis identified high-risk surgical procedure, in which the cut surface exposed the major Glisson's sheath and included the hepatic hilum (i.e., anterior segmentectomy, central bisegmentectomy, or total caudate lobectomy), as the independent predictor of the development of postoperative bile leakage. None of the 102 cases in which an intraoperative bile leakage test was performed were subsequently complicated by postoperative bile leakage, and the preventive effect of the test was statistically significant. Patients with fisterographically demonstrable leakage from the hepatic hilum and with postoperative uncontrollable ascites had poor outcomes.

Conclusion
Patients with bile leakage from the hepatic hilum and postoperative uncontrollable ascites tend to have a poor prognosis. Therefore, especially when a high-risk surgical procedure is performed in patients with liver cirrhosis, more careful surgical procedures and use of an intraoperative bile leakage test are recommended.

Because of recent advances in liver surgery, hepatic resections are being performed with increasing frequency, and the surgical death rate for such resections is decreasing.[1–7] Bile leakage, of course, is the primary complication occurring after liver surgery, and it can not only debase the quality of the postoperative course of patients, but also can lead to hospital death. Despite a significant decrease in the overall surgical complication rate in hepatic resections, the rate of bile leakage has not changed, with an incidence of 4.8% to 7.6% reported in recent large series.[2–8] The presence of bile, blood, and devitalized tissues in the dead space after hepatectomy may provide the ideal environment for bacterial growth and impair the normal host defense mechanisms.[9, 10] The combination of sudden reduction in the liver volume and development of an intraperitoneal septic complication after hepatectomy (IPSCH) frequently results in liver failure, leading to a grave prognosis.[11]

The aims of this study were, therefore, to clarify the perioperative risk factors for postoperative bile leakage after hepatic resection, to evaluate the intraoperative bile leakage test as a preventive measure, and to propose a treatment strategy for postoperative bile leakage according to the outcome of these patients.

PATIENTS AND METHODS

Charts of the 781 patients who had undergone hepatic resection in the Second Department of Surgery at Kyushu

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Accepted for publication March 14, 2000.

Table 1. INDICATIONS FOR HEPATIC RESECTIONS AND INCIDENCE OF BILE LEAKAGE

Diagnosis	n	Bile leakage
Malignant neoplasia	712	29 (4.1%)
Hepatocellular carcinoma	604	24 (4.0%)
Cholangiocarcinoma	30	1 (3.3%)
Metastatic liver tumor	78	4 (5.1%)
Benign lesions	69	2 (2.9%)
Hemangioma	22	1 (4.5%)
Other benign liver lesions	47	1 (2.1%)

University Hospital between January 1985 and June 1999 were reviewed. The indications for hepatic resections and the ratio of postoperative bile leakage are shown in Table 1. Hepatic resections with extrahepatic biliary resection and reconstruction were excluded from this study.

In most of the cases included, preoperative cholangiography was not performed. In almost all hepatic resections, division of the ipsilateral branch of the Glisson's sheath was performed in preparation for hemivascular occlusion. In 1985 and 1986, the crushing clamp method was used to transect the liver parenchyma, and since 1987 an ultrasonic dissector has been used for hepatic resection; from 1987 to 1995, the SONOP SUS201D dissector (ALOKA, Tokyo, Japan) was used, and from 1996 to present, the CUSA system (Valleylab, Boulder, CO) has been used. In the 102 cases after April 1997, an intraoperative bile leakage test was routinely performed. The bile leakage test consisted of injection of approximately 20 to 40 mL (20 cc per vial) diluted indocyanine green solution by means of a HAKKO disposable cholangiography catheter (fluoric resin; HAKKO, Tokyo, Japan) of approximately 4F in diameter with the rib on the tip of the tube to be inserted into and fixed in the cystic duct, which was intentionally preserved long after cholecystectomy. During this test, the common bile duct was manually clamped by the surgeon's fingers. With this procedure, we could recognize small bile leakage sites on the cut liver surface and could repair these sites, mainly by Z-suturing using 5–0 or 6–0 PDS*II (Johnson & Johnson Medical k. k., Tokyo, Japan) sutures. Throughout the study, fibrin glue was routinely applied to the raw cut surface of the liver to promote hemostasis and to prevent occult bile leakage. Drainage was usually by means of two Penrose drains. Drains were removed when the drainage was serous and not bile-stained, usually around the fifth postoperative day. Unless clinically contraindicated, systemic antibiotics (usually second-generation cephalosporin) were routinely given until the fourth or fifth postoperative day. For purposes of this study, postoperative bile leakage was defined as the drainage of macroscopic bile from the surgical drains for more than 7 days after surgery.

To identify the perioperative risk factors for postoperative bile leakage after hepatic resection, the 679 patients on whom an intraoperative bile leakage test was not performed were compared with respect to the following variables. There were 22 patient variables (sex; age; presence of hepatitis B antigen, hepatitis C antibody, previous surgery, diabetes mellitus, hypertension, preoperative ascites, or liver cirrhosis; hemoglobin level; white blood cell count; serum level of total bilirubin, albumin, asparaginic acid aminotransferase, alanine aminotransferase, urea, and creatinine; creatinine clearance test; prothrombin time; hepaplastin test; indocyanine green retention rate at 15 minutes; and Child grade), 7 surgical variables (type of hepatic resection, resected liver volume, concomitant cholecystectomy or bowel resection, total ischemic time of cutting of the liver surface, surgical time, and surgical blood loss), and 5 tumor variables (tumor diameter, diagnosis of malignant liver tumor, diagnosis other than hepatocellular carcinoma, solitary tumor, and tumor with portal or vein invasion). Continuous variables were expressed as mean ± standard error of the mean and compared using the Student *t* test. Categorical variables were compared using either the chi-square test or the Fisher exact test, as appropriate. Variables significant at $P < .05$ on univariate analysis were subjected to stepwise logistic regression analysis to identify the independent predictors for development of postoperative bile leakage, using a Statview 5.0 statistical software package (Abacus Concepts, Berkeley, CA).

We retrospectively evaluated the preventive effect of our intraoperative bile leak test by comparing 102 cases in which the test was performed with 679 cases in which it was not using the chi-square or the Fisher exact test, as appropriate.

Patients with postoperative bile leakage were classified into the following three groups so that we could analyze their clinical course and evaluate their management: patients with controllable bile leakage (n = 13; 41.9%) were those who were healed within 4 weeks after surgery; patients with uncontrollable bile leakage (n = 18; 58.1%) were those who were not healed within 4 weeks after surgery; and patients with intractable bile leakage (n = 7; 22.6%) were those who required more than 8 weeks to heal or who died.

RESULTS

Incidence

Bile leakage occurred in 31 (4.6%) of 679 hepatic resections. Bile leakage occurred every year between 1985 and 1997 (3.1–6.9%). In 1985 and 1986, when an ultrasonic dissector was not used, the incidence of bile leakage was not significantly high (4.8%). Since 1997, none of the 102 cases in which an intraoperative bile leakage test was performed

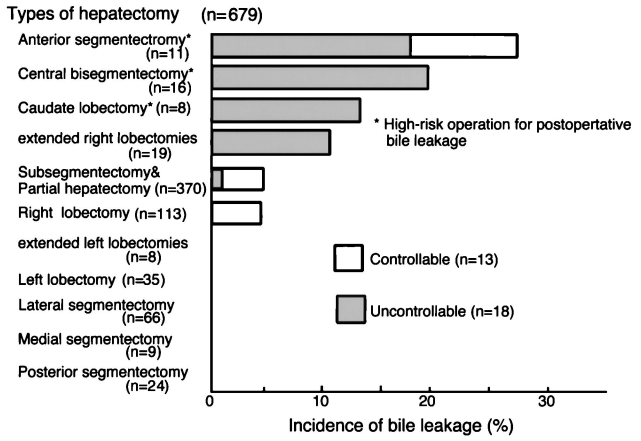

Figure 1. Types of hepatectomy related to the incidence of postoperative bile leakage.

was complicated with postoperative bile leakage. Five surgeons performed the hepatectomies between 1985 and 1996, and two of them performed hepatectomies between 1997 and 1999. Before 1997, all surgeons performing hepatectomies had approximately equal rates of incidence of bile leakage.

The relation between the types of hepatectomy and bile leakage is shown in Figure 1. Hepatectomies in which the cut surface exposed the major Glisson's sheath and included the hepatic hilum, such as anterior segmentectomy, central bisegmentectomy, and total caudate lobectomy, were found to be at high risk for postoperative bile leakage. In this study, therefore, such procedures were defined as having high risk for the development of postoperative bile leakage. When compared with patients without bile leakage, those with bile leakage were at increased risk for hospital death (6.5% vs. 1.2%; $P = .07$).

Risk Factors

High-risk procedure, intraoperative blood loss, and surgical time were associated with the development of postoperative bile leakage using univariate analysis. Stepwise logistic regression analysis identified high-risk procedure as the independent risk factor for development of bile leakage (Table 2 and Table 3).

Table 2. RISK FACTORS ASSOCIATED WITH BILE LEAKAGE (UNIVARIATE ANALYSIS)

Variable	Bile Leakage (n = 31)	No Bile Leakage (n = 648)	*P* Value
High-risk procedure	7 (22.6%)	28 (4.3%)	<.01
Intraoperative bleeding (g)	2,742 ± 336	1,764 ± 86	<.05
Surgical time (min)	343 ± 19	291 ± 5	<.05

Table 3. RISK FACTOR ASSOCIATED WITH BILE LEAKAGE (MULTIVARIATE ANALYSIS)

Variable	Coefficient	Standard Error	*P* Value	Odds Ratio
High-risk procedure	1.61	0.38	<.01	5.0

Preventive Measures

None of the 102 cases in which an intraoperative bile leakage test was performed was complicated with postoperative bile leakage, and the preventive effect on the development of bile leakage was statistically significant (0% vs. 4.6%; $P = .03$). Univariate analysis was used to compare 22 variables between the 102 cases with and the 679 cases without intraoperative bile leakage test. The ratio of high-risk procedure was not significantly different between these groups ($P = .13$). The blood loss in patients for whom an intraoperative bile leakage test was performed was less than in those for whom an intraoperative bile leakage test was not performed ($P < .01$). The surgical time of patients for whom an intraoperative bile leakage test was performed was significantly longer than in those for whom an intraoperative bile leakage test was not performed ($P < .01$) (Table 4).

Clinical Characteristics of Patients With Intractable Bile Leakage

The clinical course and characteristics of seven patients with intractable bile leakage are summarized in Table 5. High-risk surgical procedures were performed in most of these cases, and they were subsequently complicated by postoperative uncontrollable ascites. Two of these cases (6.5%) were subsequently complicated with bile peritonitis as a result of uncontrollable ascites, and reoperation was not an option because of the developing postoperative liver failure.

Evaluation of the Management of Bile Leakage

Our treatment strategy for postoperative bile leakage after hepatic resection is shown in Figure 2. Eight cases (25.8%)

Table 4. COMPARISON OF PATIENTS WITH BILE LEAKAGE TEST AND THOSE WITHOUT

Variable	Bile Leakage Test (n = 102)	No Bile Leakage Test (n = 679)	*P* Value
High-risk procedure	9 (8.8%)	35 (5.2%)	.13
Intraoperative bleeding (g)	1,046 ± 69	1,818 ± 84	<.01
Surgical time (min)	334 ± 14	294 ± 4	<.01

Table 5. CLINICAL COURSE AND CHARACTERISTICS OF PATIENTS WITH INTRACTABLE BILE LEAKAGE

Age/Sex	Diagnosis	Procedure	Clinical Course	Outcome
53/M	HCC	S8 subseg.	Ascites, bile peritonitis	Died (day 65)
53/M	CCC	Extended left lob.	Ascites, bile peritonitis	Died (day 27)
59/F	HCC	Caudate lob.	Ascites, prolonged fistula formation	Healed after 65 days
57/M	HCC	Anterior seg. Caudate lob.	Ascites, reoperation (day 19), endoscopic sphincterotomy	Healed after 72 days
66/M	HCC	Caudate lob.	Drainage only	Healed after 326 days
44/F	Recurrent hemangioma	Right triseg.	Stenosis of left hepatic duct, cholangitis, reoperation (day 104)	Healed after 132 days
69/M	HCC	Central biseg.	Drainage only	Healed after 100 days

CCC, Cholangiocellular carcinoma; HCC, hepatocellular carcinoma; lob, lobectomy; seg, segmentectomy.

were complicated by minor bile leakage (a small amount of bile leakage, or an amount that decreased daily), and in all of these patients leakage was controllable by drainage only. The other 23 cases (74.2%) were complicated by major bile leakage (a large amount of bile leakage that did not decrease daily); 4 cases (17.4%) were further complicated by postoperative ascites such that localization of intraperitoneal bile was impossible. Of these latter four patients, two died of postoperative liver failure without any treatment for bile leakage. Reoperation was performed in only one of the four patients, and primary closure of the leakage site was attempted but was unsuccessful because of the intraperitoneal dense adhesion. In this patient, endoscopic sphincterotomy was successfully performed after reoperation, and this patient was discharged on postoperative day 72. Another one of the four patients was followed up by drainage only because IPSCH was not found, but this patient's condition was eventually deemed intractable because of the delay in fistula formation.

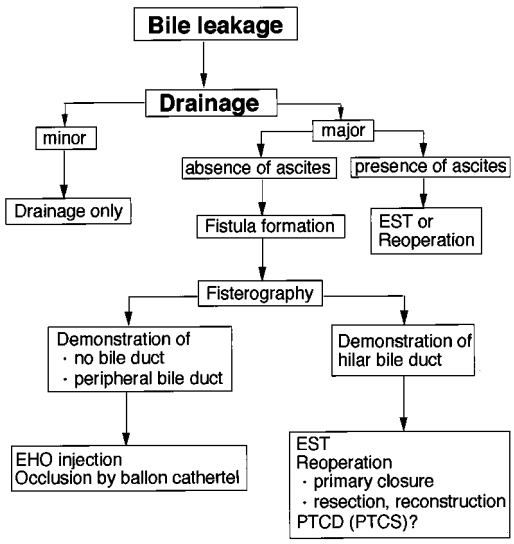

Figure 2. Recommended treatment strategy for postoperative bile leakage after hepatic resection.

In 20 patients who had a large amount of bile leakage after fistula formation of approximately 10 days, an attempt was made to identify the site of bile leakage using fisterography through the percutaneous drains. In 9 patients the bile duct was thus demonstrated, and 11 patients had fisterographically nondemonstrable bile leakage. Eight of nine patients (89%) in whom the bile duct was fisterographically demonstrable had uncontrollable bile leakage, but this rate of incidence of uncontrollable bile leakage was not significantly different from the rate (55%; 6/11) of those with fisterographically nondemonstrable bile leakage ($P = .1$).

Two of the 5 patients (40%) with bile leakage from the peripheral bile duct as revealed by fisterography and 10 of the 11 patients (90.9%) with nondemonstrable bile leakage healed spontaneously by drainage only. Ethanol injection therapy was performed in another three patients (60%) with bile leakage from the peripheral bile duct as revealed by fisterography because the amount of bile leakage did not decrease. All three patients healed within 1 to 2 months. One of 11 patients (9.1%) with nondemonstrable bile leakage did not heal by drainage only, and this patient's condition eventually became intractable. This patient was treated by a high-risk surgical procedure (caudate lobectomy), and thus ethanol injection therapy was not performed to avoid coagulation of the major hepatic duct. Balloon catheter occlusion was performed, and reduction of the bile leakage was clearly accelerated.

All four patients with fisterographically demonstrable bile leakage from the hepatic hilum (including one patient in whom the leakage occurred after reoperation) had ultimately intractable bile leakage. One of them had stenosis of the left hepatic duct after right trisegmentectomy; because this case was further complicated by sepsis from cholangitis and the percutaneous biliary drainage was unsuccessful, reoperation was performed on the postoperative day 104. Although this procedure was extremely difficult, the stenotic left hepatic duct was successfully resected and reconstructed, and the patient was discharged on the postoperative day 132. Another two of these four patients were

postoperatively followed up by drainage only; these cases were not complicated by IPSCH, but both patients went on to develop intractable bile leakage.

DISCUSSION

To our knowledge, few reports have been published on the risk factors for bile leakage after hepatic resection. Using univariate and multivariate analysis, our results showed that a high-risk surgical procedure was an independent risk factor for the development of bile leakage. During such a high-risk procedure, there are likely to be many opportunities to damage the major Glisson's sheath around the hepatic hilum. Lo et al[12] reported that left-sided major hepatectomy was an independent risk factor for the development of postoperative bile leakage because of the risk of damaging the right posterior segment bile duct drain into the left duct.[12] However, our retrospective study included few such cases. With regard to the low incidence of bile leakage in cases of left-sided hepatectomy, we think this may be due to either the stomach's or the greater omentum's easily covering the cut surface in such a case.

It has previously been reported that the intraoperative bile leakage test cannot exclude the possibility of postoperative bile leakage, because damage to the bile ducts of a small segregated segment of the liver may continue to cause bile leakage without communication with the main biliary tree.[14] Lo et al[13] also assessed the efficacy of a bile leakage test using diluted methylene blue solution through the cystic duct, but their results were not particularly favorable: postoperative bile leakage occurred in 28 (8.1%) of 347 patients. In the present study, none of the 102 patients who received an intraoperative bile leakage test developed postoperative bile leakage. Had it occurred, the amount of bile leakage from the bile ducts of a small segregated segment of the liver would be small, and the site of bile leakage would close spontaneously in the short term. In addition, we tried to repair the leakage site as much as possible using 5–0 or 6–0 PDS*II sutures of only the bile duct surface. From the analysis of the background data, however, patients for whom the bile leakage test was performed tended to be have less intraoperative bleeding and a longer surgical time. The reduction in intraoperative bleeding in patients who received a bile leakage test may have been due to the selective vascular exclusion technique,[15] which, in many cases since approximately 1996, has been used during hepatic resection to prevent blood loss from the hepatic vein. The increased surgical time in patients who received an intraoperative bile leakage test may have been due to not only the careful performance of the intraoperative bile leakage test and careful repair of the leakage site but also to the time required to dissect the roots of hepatic veins. Clearly, accurate evaluation of our intraoperative bile leakage test will require further studies, including a prospective randomized trial.

The results of nonoperative management of bile leakage after liver transplantation[16] and other hepatobiliary procedures[17,18] are encouraging, and nonsurgical measures have become the preferred approach. In our study, 29 (93.5%) of 31 patients with postoperative bile leakage were treated mainly by nonoperative measures: drainage only in 16 patients, drainage with irrigation in 9 patients, occlusion by balloon catheter in 1 patient, and ethanol injection therapy in 3 patients. Because drainage of intraperitoneal bile is of primary importance, the presence of intraperitoneal bile must be assessed during the postoperative course by ultrasonography or computed tomography, and when insufficiency of bile drainage is recognized, new subcutaneous drains must be added. Bacteria from drained bile must be checked frequently for the prevention of IPSCH, and systemic antibiotics should be used according to the result of the culture of the drained bile. However, the presence of postoperative ascites is important for the localization of the intraperitoneal bile. Two of four patients with postoperative ascites died of the postoperative liver failure as a result of IPSCH. Therefore, in cases of bile leakage complicated by a large number of ascites, early determination is crucial to perform an endoscopic sphincterotomy or reoperate to prevent the development of IPSCH.

The present study demonstrated that fisterography is helpful in determining whether bile leakage will be controllable. If fisterography demonstrates bile ducts, bile leakage tends to be uncontrollable, because the hole in the bile duct tends to be larger. All four patients with fisterographically detected bile leakage from the hepatic hilum had an intractable condition. In addition, a review of 77 cases of endoscopic management of postoperative bile leakage,[17] mostly after cholecystectomies, suggested that the site of leakage might be related to the success of endoscopic treatment. For all nonsurgical treatments, the site of leakage probably has prognostic significance. The amount of bile leakage from small ducts on the raw cut surface is usually slight, and the sites of leakage may close spontaneously or by nonsurgical measures when the main ducts are patent and biliary drainage is facilitated. Leakage from the main biliary duct is a more serious problem, because it is difficult to accomplish biliary decompression by means of only subcutaneous drainage or endoscopic therapy. The use of ethanol injection therapy is problematic in such patients.

Because fistula formation would be accomplished in approximately 10 days, fisterography should be recommended for recognizing the expansion of the cavity and the point of the damaged bile duct. When no bile duct or peripheral bile ducts are fisterographically demonstrated, ethanol injection through the drains to coagulate the fistula would be recommended. In our study, ethanol injection therapy was performed in three patients with bile leakage from the peripheral bile duct as revealed by fisterography, and all of them healed within 1 to 2 months. If ethanol injection would be ineffective or when damage to the hilar bile duct cannot be ruled out, the exit of the fistula should be occluded by a balloon catheter to retard the drainage to the skin and to facilitate the drainage to the common bile duct. Otherwise,

if the hilar bile duct is fisterographically demonstrated, bile drainage to the common bile duct is likely to be difficult, and most of these cases tend to be intractable. Thus, endoscopic sphincterotomy or reoperation (primary closure, if possible, and damaged bile duct resection with reconstruction) would be ideal, but in some cases reoperation is likely to be difficult because of dense adhesions, and endoscopic sphincterotomy is also predicted to be ineffective. Although not attempted here, a recent report indicates that percutaneous transhepatic biliary drainage is particularly useful in cases in which surgical or endoscopic management has failed.[19]

In the present study, reoperation resulting from postoperative bile leakage was complicated by dense adhesions[20] that rendered dissection and identification of the leakage site difficult; this was particularly true in patients in whom the decision to reoperate was made late in the postoperative period. The traumatization of many different tissues and the associated bleeding aggravate hepatic failure and lead to a dismal prognosis. Two patients in our study (6.5%) underwent reoperation on postoperative days 19 and 104, respectively. Both reoperations were extremely difficult, and one ended in failure to locate and repair the leakage site. Therefore, for patients with demonstrable bile leakage from the hepatic hilum and nonlocalized bile collection with uncontrollable ascites after hepatic resection, the decision for reoperation should be made as early as possible, preferably before the development of severe intraabdominal sepsis and dense adhesions. Thus, in the case of a high-risk surgical procedure with many opportunities to damage the hilar bile ducts, more careful surgical procedures should be used, and preventive measures such as an intraoperative bile leakage test should be used.

In conclusion, our results showed that bile leakage after hepatic resection was associated with a high risk for liver failure and surgical death. In patients with demonstrable leakage from the hepatic hilum and with uncontrollable ascites after hepatic resection, fistula formation and localization of intraperitoneal bile, and thus healing of bile leakage sites, are likely to be difficult. For this reason, more careful surgical procedures, such as ligation of the small bile ducts around the hepatic hilum, and use of the intraoperative bile leakage test are recommended when high-risk procedures are performed.

Acknowledgment

The authors thank Naoko Kinukawa, Department of Medical Informatics, Kyushu University, for her critical comments and advice on the multivariate analysis in this study.

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